Rijksinkoopsamenwerking
Ministerie van Binnenlandse Zaken en Koninkrijksrelaties

Market Consultation Document

Rijksinkoopsamenwerking (RIS)

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Market Consultation

Lead auditor GAPIV audits polio facilities

on behalf of

Ministry of Health, Welfare and Sport
Health and Youth Care Inspectorate (IGJ)

Contacts	Ms. W. Shing
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Appendices

To be completed and/or added electronically by supplier in TenderNed		
Appendix 1	Question form for information notice	In accordance with the attached form
Appendix 2	Response template to questionnaire	In accordance with the attached form

1 Introduction

As the Contracting Authority, Ministry of Health, Welfare and Sport, in particular the Health and Youth Care Inspectorate (IGJ) wants to explore whether there are interested parties to perform the Global Action Plan for Poliovirus Containment (GAPIV) audits for the facilities in the Netherlands working with poliovirus.

We can use the gained information to determine the most appropriate tendering procedure. Market parties on the other hand benefit from the fact that they can get a glimpse of the Contracting Authorization as an organization and they can express their interest.

We invite you to respond to this Market Consultation if you are qualified and interested.

1.1 The Contracting Authority (IGJ)

Everyone in the Netherlands should be able to rely on good healthcare and youth care. The kind of care that you would want for yourself and your loved ones, in every situation and throughout every phase of life. Our role is to supervise healthcare and youth care services in the Netherlands and the international market for medicines and medical devices. We make sure that these comply with the relevant legal and regulatory standards, and we do this in a clear manner. We also promote good and safe care. Besides that we encourage care providers to work on prevention, cooperation and continuous access to healthcare and youth care services. For more information about IGJ, you can consult their website: Home | Health and Youth Care Inspectorate (igj.nl).

Rijksinkoopsamenwerking (RIS) is supervising this Market Consultation

The RIS has been commissioned to supervise this Market Consultation. The RIS is a civil service organization specialized in the procurement of services and products. If you would like to know more about how the RIS works, please read Business Etiquette "Zo doen we zaken" [This is how we do business] on the RIS website.

1.2 Contact

Your Contact is ms. W. Shing, project secretary RIS. For this formal Market Consultation we would like to maintain clear rules, comparable to a tender. This is why we would like you to communicate only with the Market Consultation Contact and request that such communication is done via TenderNed.

1.3 Structure of the Market Consultation Document

This document is intended to clarify the procedure, conditions, methods and intentions of the Market Consultation. This document contains an explanation of the consultation procedure, background information of the project and a formulation of questions to the participating parties.

In chapter:

- 2: we provide an outline of the contents of the potential assignment and our questions;
- 3: we describe the procedure followed by the Contracting Authority in this Market Consultation;
- 4: the applicable limiting conditions and starting points of the Market Consultation are listed.

Finally, there is a glossary which explains exactly what is meant by certain terms. In the text itself, such terms are always shown with a capital letter. This indicates which terms can be found in the glossary.

In addition, a few Appendices have been provided for the following purpose:

- Appendix 1 is used when you have questions for the Contracting Authority; and
- Appendix 2 is used to share your answers with the Contracting Authority.

2 What is the topic of the Market Consultation?

This chapter describes the scope of the potential assignment and entails the questions that we have.

2.1 What is the background and context of the Contract?

Since 2019, the IGJ has been assigned the task of the NAC (National Authority for Containment). In short, the Netherlands has signed a WHO resolution by which the Netherlands commits to the implementation of the Global Action Plan (GAPIV) to eradicate polio from the world. Part of that plan is certifying facilities that work with poliovirus. The requirements that a facility must meet are included in GAPIV. The NAC will conduct audits to test whether a facility meets the requirements in order to issue a certificate, and ultimately a permit.

The WHO only certifies facilities when audits have been carried out by (lead) auditors recognized by the WHO. The IGJ wants to have the audits carried out in accordance with WHO standards and therefore wants to contract a, by WHO approved, lead auditor.

2.2 What is the scope of the Contract?

In the Netherlands there are five facilities that work with poliovirus. These facilities must be audited against WHO GAPIV requirements. A facility can only obtain a certificate from the WHO if the requirements are met. The IGJ/NAC is responsible for assessing the requirements and requesting the certificate from the WHO. The IGJ does not have (certified) auditors at the moment nor the technical knowledge required to test the technical systems of the facility. This mainly concerns knowledge about technical systems, such as pressure hierarchy, water drainage, air management, and gas decontamination. Because it concerns only a part of the audit, it is not appropriate to employ a technical expert, which is why this is included as part of the contract with the lead auditor.

The audit must be carried out based on WHO standards. These requirements[1] are recorded in GAPIV, which is divided into fourteen (14) elements. All elements must be tested during the audit. Prior to the audit, documents are requested at the facility, these are reviewed and serve as a basis for the checks that take place during the audit. The audit itself generally lasts two (2) weeks on site at the facility and consists of interviews of employees and observations of the various areas of the facility. The audit starts with an opening meeting with the organization in question and ends with a closing meeting. In both cases a presentation is given by the lead auditor. The shortcomings (non-conformities) are presented particularly in the closing meeting. The results of the audit are recorded in the formats established by the WHO. The lead auditor is involved in the entire process, but is mainly responsible for conducting the interviews and touring the various areas of the facility.

During the term of the contract, the interviews will be taken over by the NAC team members. The lead auditor is also responsible for determining which external expertise should be connected based on the document review and also arranging this. This mainly concerns the technical expert because this is very specific knowledge.

To summarize, the main services consists of:

- Pre-review of audit documents;
- Advising and providing feedback on shortcomings within the facilities;
- Delivery of an audit report in accordance with the WHO GAPIV requirements for each facility;
- Giving a presentation during the opening and closing meeting;

[1] WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf (polioeradication.org)

- Giving input/feedback on the facility's root cause analysis and corrective action plans regarding the elimination of shortcomings and the follow-up process;
- Giving input/feedback on the risk assessments of the facility.

The lead auditor should have experience with:

- Extensive knowledge and experience of audit processes;
- Preferably experience with GAP IV or at least GAP III;
- Extensive knowledge and experience with the RA's (Risk Assessment) and RCA's (Root Cause Analysis) and CAPA (Corrective and Preventive Action);
- Training and guidance of auditors.

2.3 What questions does the Contracting Authority have?-

The Contracting Authority mainly wants to assess whether there are interested parties that can provide the described services and have substantial experience with these types of audits.

Questions about the Contract

1. Considering the context and description of the required experience, are you interested and capable of delivering the services of Contract?
2. Can you give a brief overview of your relevant experience?

3 What is the course of the procedure?

This chapter describes everything about the procedure of the Market Consultation. You will be given an overview of the planning. Each step is then explained briefly. This chapter also describes how you can ask questions.

3.1 The Market Consultation

Every Relevant Market Party may participate in this Market Consultation

For more general information please visit the following website:

www.rijksoverheid.nl/onderwerpen/aanbesteden.

This Market Consultation concerns services with the following CPV codes:

- 79212000-3 Auditing services;
- 85100000-0 Healthcare services.

This Market Consultation consists of one phase, namely only a written phase.

3.2 Market Consultation planning

Below is the planning of the procedure. The following sections provide a brief explanation at each part.

Activity	Date and time
Submitting questions	Monday 20th of November 2023, 11:00 CET
Publication of Summary of Additional Information and Changes	Monday 27th of November 2023
Submission of responses to the Market Consultation questions	Monday 4th of December 2023, 11:00 CET

3.3 Questions about the Market Consultation

It may be that something in the Market Consultation Document is unclear to you. This section explains what you can do.

Ask all your questions via TenderNed
Do you have any questions on the contents or procedure of this Market Consultation? Then ask those questions via TenderNed. For this purpose, please fill in Appendix 1 – Question form for information notice. We do not answer questions posed over the phone.

Send all your questions and suggestions by Monday 20th of November 2023, 11.00 CET.
This will ensure that you will get an answer to your question. If you send your question or suggestion later, then there is no guarantee that your question will be answered.

Any names mentioned with your questions and suggestions are at your own discretion
For your questions, you are free as to what extent you make use of:

- company names
- product names
- other names that are related to your organisation.

All the questions and answers are published on TenderNed
All the questions and answers will be available in the Summary of Additional Information and Changes. In this way, all Relevant Market Parties get an equal amount of information. You will

receive an email at the time that we publish the questions and answers. We will publish the Summary of Additional Information and Changes by no later than Monday 4th of December 2023.

Confidential questions may also be posed
However, the answer is then only intended for you, and not for other Relevant Market Parties. This means that we do not publish this on TenderNed. Would you prefer to receive a confidential answer to your question? Please motivate clearly why you believe that disclosure of this information would damage the legitimate economic interests of your company. If we do not agree with your motivation, we will contact you.

If we believe that the relevant question does not qualify for this, then you will be given the opportunity to withdraw the question. If you do not withdraw the particular question, then we will deal with it and publish the answer anonymised on TenderNed.

We will only provide you with information via TenderNed
If you receive information in a different way, then no rights can be derived from it. This also applies if you get information from your RIS Contacts outside TenderNed.

3.4 Submission of response to Market Consultation

Submit your response to the Market Consultation at the latest by Monday 4th of December 2023, 11:00 CET
You can only submit your response via TenderNed. This is done by adding your response in a message to us in TenderNed. It helps if your response meets the following conditions:

- You respond to the answers provided by us by using the response form (Appendix 2).
- You submit your response in a Microsoft Word file or Open Text file and in PDF form.

If you do not want to answer a certain question, then please let us know why, so that we can understand the underlying reasoning. By submitting a response to this Market Consultation you agree to all the terms and conditions of this Market Consultation. You are free to add any additional documents to your response.

3.5 Contracting Authority reservations

The Contracting Authority may stop this Market Consultation at any time
Should it be decided to do so, you will be notified via TenderNed. In addition, the Contracting Authority has the right at all times to amend, alter and/or expand the Market Consultation.

The Contracting Authority does not reimburse costs
All costs associated with this Market Consultation are for your own account. Any loss caused due to participation in this Market Consultation is at your own risk.

4 What are the starting points and limiting conditions for this Market Consultation?

This chapter describes the starting points and limiting conditions applicable to this Market Consultation. By participating in this Market Consultation, you agree unconditionally with reservations, starting points and limiting conditions as stated in this Market Consultation Document. The starting points and limiting conditions have been listed below:

- In this Market Consultation procedure, the Contracting Authority will observe the principles of non-discrimination and transparency, as meant in the Public Procurement Act 2012 [*Aanbestedingswet 2012*];
- This Market Consultation Document is solely intended for Market Consultation purposes;
- This Market Consultation will explicitly not be used to make a pre-selection of candidates or interested Relevant Market Parties in the context of an intended tender;
- Relevant Market Parties who do not participate in the Market Consultation will not be excluded from further participation in a potential procurement procedure. Relevant Market Parties who do participate in the Market Consultation do not exclude themselves in any manner whatsoever, nor do they advantage themselves in any way for any participation in a procurement procedure;
- The Market Consultation is free of obligation both for any Relevant Market Parties and for the Contracting Authority;
- Participating Relevant Market Parties can derive no rights or obligations from this Market Consultation against the Contracting Authority;
- Participation by a Relevant Market Party to this Market Consultation does not give any right to acquiring an assignment;
- The participating Relevant Market Parties agree that the Contracting Authority will incorporate the information provided by the Relevant Market Parties anonymised in the schedule of requirements still to be determined by the Contracting Authority;
- Information provided in the context of the Market Consultation might deviate from the information still to be issued in the tender;
- To the extent possible, the Contracting Authority will deal with input from the Participating Relevant Market Parties confidentially, in which, in any event, the Contracting Authority will keep account of the legitimate business interests of parties;
- The languages to be used in this Market Consultation is English;
- The Contracting Authority is not bound in any way whatsoever by the results of the Market Consultation, nor is it obliged to realisation and/or tendering of the project to which this Market Consultation relates;
- Under no circumstances will the Contracting Authority honour any claims for the use of information, confidentiality, or requests for remuneration;
- The documents submitted by the participating parties will be treated confidentially;
- The Contracting Authority places no value judgment on the answers given by you to the questions; and
- The Contracting Authority reserves the right to:
    - amend the planning as stated in this document;
    - implement the intended tendering procedure in terms of format and content in a manner other than the procedure that has possibly been notified; and
    - discontinue this Market Consultation tentatively or definitely.

Glossary

Some terms are used more often in this Market Consultation Document. We want to ensure that you know exactly what these terms mean. Hence the important terms are explained below.

Term	**Meaning**
Appendix	Every document with the title "Appendix" associated with this Market Consultation Document. This includes the documents on TenderNed that have "Appendix" in the title. An Appendix is part of the Market Consultation Document.
Contact	RIS Ms W.Y. Shing Project Secretary
Contract	The public contract for which this Market Consultation serves
Contracting Authority	The State of the Netherlands, in this case, the Ministry of Health, Welfare and Sport, Health and Youth Care Inspectorate (IGJ)
TenderNed	The electronic tendering platform via which this market consultation is published.
Information notice	See 'Summary of Additional Information and Changes'
Market Consultation	Posing questions to the market about a specific topic which aims to gather information. This information is possibly used by the Contracting Authority in a tendering procedure.
Market Consultation Document	This document and its associated Appendices.
Public Procurement Act	The Act of November 1th of 2012, which contains the new rules for procurement (Bulletin of Acts and Decrees 2012/542) and the Act of June 22th of 2016 amending the Public Procurement Act 2012 in connection with the implementation of procurement directives 2014/23/EU, 2014/24/ EU and 2014/25/EU (Official Gazette 2016/241).
Relevant Market Party	A service provider - according to the description provided in Section 1.1 of the Public Procurement Act 2012 - which is also a financial institution (within the meaning of the Dutch Financial Supervision Act) who is permitted to carry out the services as described in this Market Consultation in the Netherlands.
Summary of Additional Information and Changes or Information Notice	The document that contains: • amendments or additions to the Market Consultation Document. • our answers to your questions and those from other Relevant Market Parties. The Summary of Additional Information and Changes is part of the Market Consultation Document.
RIS	The organisation who supervises the Tender for the Contracting Authority.